

## False Positives: How Valid is DBS (PEth) Testing?

**ABSTRACT:** Phosphatidylethanol (PEth) is a *non*-FDA-approved “Laboratory Developed Test,” (LDT). Blood PEth is a metabolite of alcohol that has an extended window of detection with a half-life of 2-14 days. PEth testing has been increasingly utilized to determine alcohol consumption over a 2–4-week period, prior to testing, for those who are being monitored in an alcohol prevention program or as the result of court-ordered abstinence. While a growing rise of false positive test results has been noted, experts have testified that it is impossible to receive a false positive. As a result of that assertion, people have lost their careers, the custody of their children, and even their lives due to a positive PEth test result despite purported abstinence. This intent of this study was to determine if a positive test was possible if an individual abstained from alcohol consumption. The results of this research were conclusive that false positive test results do exist. Additional research could identify the reasons false positives occur, to include the many variables throughout the process from collection to storage and shipping and lack of standard operating procedures at the lab, but also due to the variability in human genetics and physiology. The recommendation is for heightened awareness that false positive blood PEth test results do occur, and caution should be observed in overreliance on this test as proof of alcohol consumption.

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### INTRODUCTION

Phosphatidylethanol (PEth) is a lipid metabolite of ethanol (EtOH) formed from phosphatidylcholine and ethanol by a reaction catalyzed by phospholipase D (PLD). PEth measurement has been established as an alcohol biomarker within both clinical and forensic applications, although the question of whether a positive blood PEth test is proof of drinking remains a concern. However, PEth test has been increasingly utilized to assist detection of alcohol consumption in forensic administrative settings, even though research has indicated PEth formation *after* a sample has been collected. (Beck, et al., 2021). Other possible reasons as to why a positive blood PEth test without alcoholic beverage consumption may occur is the subject of concern. Therefore, the question of the possibility of a false positive must be answered.

Currently blood samples testing for PEth can be collected via venipuncture with a whole blood sample, collected in a vacutainer tube, or via a finger prick where blood dropped onto a card, filling five circles, identified as a Dry Blood Spot (DBS) PEth test. Due the ease of collection DBS

testing has been purported to be “a game changer in alcohol biomarkers” (Lewis, 2014).

Studies have shown that significant exposure to ethanol (approximately 100 grams) is required over a period of weeks for a blood sample to test positive for PEth at a 20ng/ml, the widely used cutoff for abstinence (Helander et al., 1996; Ulwelling and Smith 2018). There is no scientific rationale for the 20ng/ml cutoff other than it was simply a random number that is utilized to identify the impact of incidental exposure.

To date, the favored assumption is that PEth detection can only occur with alcohol consumption, and that incidental exposure to environmental alcohol is unlikely to produce enough exposure for a positive PEth test. Yet studies are emerging that identify otherwise. Due to the high use of hand sanitizer because of Covid, the question of whether ethanal-based hand sanitizer could have an impact on PEth testing has become a topic of discussion.

### Hand Sanitizer

Research is limited regarding the effect of hand sanitizer on DBS PEth testing. United States Drug

Testing Laboratories (USDTL), the only laboratory that utilizes DBS PEth testing, conducted a study with only 4 volunteers, therefore they were unable to rule out either way the effects of hand sanitizer. (Jones, 2022). However, the assertion is that for hand sanitizer to effect DBS PEth results, the individual would have to either bathe in a vat of it, or drink enough to become intoxicated (Lewis, 2014). Yet research has also indicated that the use of ethanolic hand cleaner prior to DBS PEth testing has produced elevated levels of PEth (Augusburger et al., 2019).

### **PEth Testing and Pilots**

HIMS (Human Intervention Motivational Study) is a substance abuse treatment program that evolved from a 1975 study focused on airline pilots with alcohol use disorder (AUD). Present day, each airline establishes a HIMS program of their own, based upon FAA criteria and the associated union contract. Choice Labs is a middleman connecting ARCpoint labs, the collection sight of DBS PEth, to USDTL, the laboratory that analyzes pilots' blood on behalf of the airline.

Three in-house studies at Choice labs occurred to better understand DBS PEth test results with hand sanitizer, and documented alcohol consumption prior to testing. In the first test, hand sanitizer was applied throughout the day to replicate a typical nurse's exposer. Capillary blood was then collected via the DBS PEth test procedure. Test results indicated negative for PEth. Next, hand sanitizer was dripped onto the finger with the first drop of blood and another capillary blood sample was drawn via DBS. The blood tainted with hand sanitizer was placed on the first of five circles, all of which were sequentially filled. Circle one detected a PEth level of 22 ng/ml, circle two delected less than 20 ng/ml and there was no PEth detected on circles three, four, and five. This result indicated a negative test result based upon the three negatives of the five circles. The third test conducted by Choice labs was on ten lawyers. These attorneys were curious as to the quantitative numbers between the amount of alcohol and associated PEth levels associated with custody orders. Each of these attorneys consumed alcohol daily and documented their consumption. All ten attorneys were then tested for PEth via the DBS capillary collection method.

Results identified that three of the ten DBS test results were negative for alcohol consumption, despite those individuals having consumed alcohol. The recommendation from Choice Labs to the attorneys was to place their clients requiring abstinence on a mobile breathalyzer, in lieu of PEth. Choice labs also conducted multiple DBS tests on the owner of the lab, after having consumed alcohol, and reported that those tests produced negative results, despite alcohol consumption. (Personal communications, Choice Labs, Michell Gable, 2020.)

### **False Positives**

Proponents of PEth testing assert that there are no substantiated false positives (Reisfield et al., 2020). Contrary to those assertions, research has confirmed the presence of alcohol vapors during the DBS drying phase has led to false positive results. (Bashilov, et al., 2022). Additional research confirmed Tests have identified that PEth formation in wet blood post- sampling will occur; however, if the DBS filter-paper test cards were stored at room temperature for 48 hours, they were not subject to the same post-sampling formation of PEth (Beck, et al., 2021). Beck (2021) also recommended the use of a PLD inhibitor to avoid results of a positive test result that could otherwise be challenged.

Numerous anecdotal reports corroborate the growing number of individuals who have asserted they had not consumed alcohol and yet received a positive DBS PEth test. Not only is the PEth test not FDA approved, but at the time of this writing, the researcher was unable to find any validation studies regarding DBS PEth testing that could identify pre- or post-collection variables to include but not limited to hand sanitizer or sample collection processes. The methodology in which the DBS sample is obtained, dried, stored and shipped could be associated with fermentation and resulting formation of PEth.

According to the FDA, inaccurate tests have far-reaching effects when they reveal false-positive results and are equally detrimental when the LDT results in a false negative (U.S. Food and Drug Administration, 2018). Despite the FDA concerns with inaccurate test results, laboratories are not

required to report adverse events into a central database; therefore, they do not provide comprehensive data to quantify the inaccuracy of LDTs (The Pew Charitable Trust, 2021). Such events could be identified as results of false positives, identification of false negatives, or the mixing of individuals' samples.

### **Conflicting Research**

Despite those who say a false positive is "impossible" PEth has been detected post sample collection following DBS and whole blood collections (Beck et al., 2020). Whereas Reisfield et al. (2020) assert that it's unknown if interindividual differences could make a difference with incidental alcohol exposure to produce PEth, others have asserted that factors within individuals could affect Phospholipase D activity, the enzyme that creates PEth, and therefore may affect levels of PEth (Hahn et al., 2016; Krzystanek et al., 2020). Limitations have also been noted as to the inability to assess sensitivities to the biomarkers (Reisfield et al., 2020). Yet Beck et al. (2020) identified a high sensitivity to biomarkers supporting Peterson's (2004) assertion that none of the available biomarkers are ideal.

Some studies identify that there is no gender difference with the formation of PEth, due to women typically having higher fat content, with a lower hydration level, as comparable to the same weight man, due to alcohol being insoluble in fat. (Shrock et al., 2017; Helander et al., 2012; Wurts et al, 2010). However, this assumption does not take into account a pound per pound athletic woman versus an overweight male.

While PEth testing utilizes either whole blood or Dried Blood Spot (DBS) capillary collection methodologies, it appears that incidental exposure to hand sanitizers has increased the risk of the DBS collection method. (Bashilov, et al., 2022).

### **SIGNIFICANCE**

In that PEth testing is being utilized to monitor parents in custodial agreements and individuals in alcohol avoidance programs, (physicians, lawyers,

airline pilots, those in safety sensitive occupations, and individuals on an organ recipient lists), a false positive test result could have a far-reaching and devastating impact on the individual's life. When an individual tests positive for PEth, that test is considered absolute proof of alcohol consumption, and the individual is in violation of monitoring or custodial agreements. Significant sanctions are then applied including loss of the pilot's medical license, or legal licenses with associated career loss, denial of liver transplants resulting in loss of life, or forcing a parent to unjustly give up custody of his/her child(ren). Research to ascertain the validity of false positive blood PEth tests is essential to avoid unnecessary harm to those of sustained abstinence.

Experts have asserted that 400-500 PEth tests over seven or eight years have been conducted yet, there was never any assessment to the accuracy of those tests, despite numerous claims of false positive test results (Danford, 2020, p. 1122). Yet, there was no assessment to the accuracy of those 500 tests.

In that PEth is being utilized in legal cases to the downfall of those individuals who assert sobriety, taking children from parents, and denying transplants, it becomes essential to learn the truth if a false positive is possible.

### **OBJECTIVE AND METHODOLOGY**

The objective of this study was to gather data to determine if false positive DBS PEth test result could occur despite the individual not having consumed alcohol. In that proponents of DBS PEth testing believe that false positives are not possible, the goal of this research was to invalidate that assertion.

### **USDTL LABORATORY**

#### **Eliminate Variables at the USDTL Lab**

USDTL labs are the only commercial laboratory that conduct DBS PEth testing. To validate the process at the lab, Substance Abuse and Mental Health Services Administration (SAMHSA) inspector assessed the USDTL lab as a result of a legal case.

The USDTL process was observed, and standard operating procedures (SOP) were viewed to ensure they were scientifically valid and that the technicians were following SOP. The validation data were viewed specifically due to the dried blood spot tests. After spending a day at the laboratory, the inspector was assured that the testing process was accurate and a very sound forensic process (Danford, 2020, pp 1019-1020).

For the purposes of this research, the USDTL facility in Des Moines, Iowa, was not considered a contributing factor to the outcome of the test results. However; this research does not claim that there could not be human error or lack of standardization regarding the laboratory's policies and procedures.

### **Eliminate Donor Variables**

To control all the variables of the subjects donating blood, based upon diet, age, weight, fat content, gender, body chemistry, and to ensure there could be no contributing factors due to the difference in body chemistry, all samples were taken from the same participant. In that one human was used removes the possibility of any confounding variables as aforementioned beyond the collection methodology. Regardless, the goal was to determine if a false positive PEth result was possible.

### **Operational Definitions**

- ◆ A description document was a typed set of directions as to how each blood sample was to be collected.
- ◆ PEth was defined by an ng/ml level.
- ◆ Whole Blood Sample was defined as the sample taken intravenously from an arm.
- ◆ DBS Blood Sample was defined as a capillary blood sample taken by a finger prick with five drops on testing paper.
- ◆ Standard DBS testing was defined as the required protocol of blood collection, drying, and packaging methodology per USTDL standard operating procedures.
- ◆ Non-standard DBS testing was defined as a variation of the standard method of blood acquisition to include:

- (1) Testing paper folded closed, no airflow prior to packaging in the drying box,
- (2) Pressing the finger to the paper during the collection process,
- (3) Lab technician utilizing hand sanitizer prior to collection of samples, and
- (4) Lab technician milking the finger to produce blood drops on the sample paper.

### **Materials and Method**

The participant had abstained from all alcohol since June 18, 2023, to the time of collection on July 20, 2023. Five blood samples were collected from the participant. All five blood samples were drawn by a technician from ARCpoint labs in Seattle Washington and shipped to USDTL labs for processing.

USDTL utilizes a five-circle DBS filter-paper test card, taking five samples for each card, the researcher provided a total of 21 samples for testing—one vial of whole blood and 20 circles. However, for the purpose of this study, each card will be discussed as “a sample test.”

The researcher provided five blood samples of her own blood to control for variables: One whole blood draw, one capillary blood draw for a DBS PEth test drawn per USDTL standard operating procedures, and three capillary blood draws for DBS PEth tests that were manipulated contrary to the required process. The description document for each of the five samples were as follows:

1. Intravenous whole blood, following standard testing protocol,
2. Fingerpick to obtain a capillary blood draw for a DBS PEth test following standard testing protocol,
3. Fingerpick to obtain capillary blood for a DBS PEth test following standard testing protocol except for:
  - a. Folded the card prior to placing into the drying box.
4. Fingerpick to obtain capillary blood for a DBS PEth test not following standard protocol by:

- a. Using hand sanitizer,
  - b. Not wiping the first drop of blood,
  - c. Pressing the finger onto the test strip, and
  - d. Folded the card prior to placing into the drying box.
5. Fingerpick to obtain capillary blood for DBS PEth test not following standard protocol by:
- a. Using hand sanitizer,
  - b. Not wiping the first drop of blood
  - c. Milking the finger,
  - d. Pressing the finger onto the test strip, and
  - e. Folded the card prior to placing into the drying box.

All samples were placed individually into a cardboard box, and then the box was placed into a cabinet. The office was airconditioned and cool enough to need a sweater for comfort. The researcher was told that the samples would be shipped by ARC Point labs to the USDTL labs for PEth analysis that evening.

The description documents with the methodology process, numbered 1-5, were each presented to the technician as a typed document that described in detail the step for each test. The technician followed the guidelines per USDTL standard procedures on tests one and two as outlined on the description documents. The technician then followed the methodology outlined on the description documents for tests 3-5. Both the researcher and technician signed and dated each document asserting that the collection process was accomplished as described per the description documents, and that the blood for all five samples was collected from the researcher, albeit different names were added to the forms for anonymity at the lab to eliminate any bias.

If any PEth indication was present the USDTL labs would retain the samples to re-run the tests in order to confirm any positive test results. The negative test results would arrive first and positive test results later if they existed. This was the case as test results numbers 4 and 5 arrived two days after test results 1-3.

## RESULTS

- ◆ Samples taken by methodologies of one, two, and three were received on July 24, 2023, and all three indicated: **Negative**.
- ◆ Samples taken by methodologies four and five were received on July 26, 2023, and both indicated: **Positive**.
- ◆ Sample taken by methodology four identified:
  - **21 ng/ml**.
- ◆ Sample taken by methodology five identified:
  - **83 ng/ml**.

The results of samples four and five are consistent with heavy drinking weeks prior and up to the test.

## DISCUSSION

The steps utilized in test numbers four and five in this collection process were designed to replicate previous DBS PEth testing processes that have been collected for individuals in a similar manner, of whom subsequently received positive test results but argued total abstinence (Personal communications, Ratfield, 2023). While experts have contended that false positives are not possible, this research contradicts that assertion, and indicates otherwise.

All five blood samples were collected from the same participant on the same day. She had abstained from alcohol for one month. The first three of the five samples support alcohol abstinence, yet two of the samples from the very same blood tested positive, indicating that false positives in fact do exist, as a direct result of the collection method, in that all samples were placed in a similar drying box, in the same cabinet, and sent to the same lab for analysis. The variability between results appears to be the result of non-standard collection methods.

The folding of the card flat did not create PEth in test number 3, despite the requirement to maintain airflow. The technician is directed to fold the card in a manner that air will flow through it for drying in the cardboard box. However, this card folded could have lifted in the drying box unknowingly providing airflow, therefore the type of folding is inconclusive on its own. The tests that were positive, could have also remained closed, and could have been a

contributing factor to the positive test results. This too is inconclusive.

What is unknown is if pressing the finger to the paper, milking the finger, or the quantity of hand sanitizer was the primary contributing factor of the test results of 83ng/ml. One concern with a finger prick blood sample versus whole blood, taken from the arm, is that capillary blood is “polluted by fluids from tissues and cells” suggesting that the latter measurements are less accurate (Carreyrou, J., 2018. p).

The cutoff for assumed alcohol consumption is 20ng/ml. This number accounts for incidental exposure but in fact is an arbitrary number. Anything over 20 ng/ml is considered to have consumed alcohol, anything under is considered negative. There is no definitive answer as to what the numbers of 21 ng/ml and 83ng/ml equate to with the amount of alcohol consumption. Each body metabolizes alcohol a bit differently. However, a 2012 study that included 1339 participants identified that a PEth result of 73 indicated the individual drank up to 4 drinks daily (Viel, et al., 2012).

Contrary to Lewis (2014) assertion that this is a “game changer in alcohol biomarkers” due to the ease in collection, the researcher found the DBS PEth testing to be extremely time consuming in relation to the whole blood PEth test. A couple minutes to draw a vial of blood, but 10-20 minutes to get the normal sample from a finger prick. The standard procedure for a DBS PEth test requires the first drop of blood to be wiped away and the puncture sight was required was to fill five circles, approximately the size of a nickel, with blood on a card without touching it. This was problematic due to clotting and the cooler temperature of the room. The first test, the collector pricked the finger a half dozen times bruising it to enable the filling of five circles with enough blood for a sample taking approximately 20 minutes to accomplish.

The second sample the collector utilized a hot water bottle (a rubber glove filled with hot water) to warm the hand, but the process was equally as difficult by wiping the first drop and multiple pricks and took approximately the same time. The third DBS sample

was also heated but due to the ability to touch the finger to the paper and not wiping the first drop, as directed per the description document, the process was a bit quicker, approximately 15 minutes. Finally, the fourth DBS collection, also warmed, with milking the finger, multiple pricks, and touching the card to the paper, as directed per the description, document, enabled a far quicker process than the “normal” DBS collection method approximately 10 minutes. Milking the finger was a time saver.

The results obtained in this research provide evidence against the assertion that a false positive is impossible. There is no question that the participant abstained from alcohol to have received three negative PEth tests, with the same blood as those that were positive. The same blood gathered with different steps produced different results. Two positive test results by someone who was verified to have abstained from alcohol, not only by her self-disclosure, but also verified by the first three tests that indicated negative, identifies false positives exist.

This pilot study did not determine the reasons as to *why* there were two false positive test results, only that false positive test results do exist by the methodology of capillary blood collection indicating that hand sanitizer, pressing the finger to the paper, and/or or milking the finger somehow created a false positive test result. There was no research conducted as to which of the variables induced, or a combination thereof, or the quantifying the amount of hand sanitizer utilized was the reason for the false positive. This research only attempted to determine if it was possible to obtain a false positive.

This research, albeit limited by a small sample, should open the door for additional studies as to what causes false positive test results, to include testing in different geographical locations, perhaps with higher humidity than Seattle Washington, collection in a non-airconditioned room, with a variety of people, to determine a variance in a person’s metabolism and chemistry, and to introduce a variety of foods into the diet in effort to find the causal link of false positives. The sample itself is also required to dry for one hour prior to bagging. If a drying box is placed directly into a plastic bag for shipping, due to the test being

taken at the end of the day, this could also impact results according to the USTDL named procedures advising drying procedures.

Interviews with those who have received what they claim to be false positive test results have identified that their tests were “bagged up” and sealed immediately, or they simply did not stay to watch the ensuing process. Furthermore, prior to placing a blood specimen into a plastic bag, desiccant packs should be added to absorb moisture, and whether that happens is unknown.

The question to the validity of a study utilizing one human with five sample tests would be a valid concern if this research was to determine what caused false positives. However, this research was to test the *possibility* of a false positive; therefore if 2000 people participated, but only one person tested positive, the results would still identify the possibility of a false positive, albeit less likely. In this case, only one person participated, and two of the five tests reported false positive, indicating not only is possible but also likely to occur.

## LIMITATION

A significant limitation of this study was the lack of multiple participants. However, the *only* goal of this research was to determine *if* a false positive was possible, and not the frequency of those events or the reasons attributing to the results. Thus, even with a larger sample, the results would still show evidence for a false positive.

## CONCLUSION

Had the participant who was involved in this study been mandated to take a DBS PEth test and subsequently received either of the two tests that she received as positive she would have lost her pilot’s license, her career, the custody of her children, and/or her life, depending upon the reason she was being monitored, when in fact she had not consumed *any* alcohol.

There is no greater crime than to “try and convict” an innocent person with such far reaching and devastating impact to their life. With respect to

aviation safety, in that the owner of Choice labs conducted research that identified three out of ten individuals who drank for a month still tested negative for PEth, the unreliability of a monitoring system designed to keep alcohol out of the flight deck has failed. Suggestion of a mobile breathalyzer should be heeded.

This study showed that two false positive tests resulted despite alcohol abstinence. Ten blood spots out of twenty detected PEth. Therefore; false positive test results do exist with the DBS PEth test.

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